

## **Remarks{tc "Remarks"}**

The various parts of the Office Action (and other matters, if any) are discussed below under appropriate headings.

### ***Drawings***

The Examiner objected to the drawings because page 9 lines 21 and 22 describe numeral 45 as the inner sheath but Figure 4 did not show numeral 45 as pointing to the inner sheath. Figure 4 has been amended so that reference numeral 45 now points to the inner sheath and further to show the openings at the ends of the sheaths. Support for this amended Figure 4 can be found in the originally filed application at page 9, lines 6 to 22. In view of the foregoing, withdrawal of this objection is requested.

### ***Specification***

The Examiner has objected to the specification because of several typographical errors. The specification has been amended to fix the typographical errors, and request is made for withdrawal of this objection.

### ***Claim Rejections - 35 USC § 112***

Claims 1-10, 18, 20 and 21 were rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, the Examiner contends that claim 1 is unclear with respect to the definition of the stiffness of the guidewire. The Examiner considers that it is unclear whether the force mentioned in claim 1 is to be applied at a point 10 mm along the respective length of the guidewire, or is to be uniformly distributed along this 10 mm length.

Claim 1 has been amended to more clearly define the stiffness of the guidewire as "the force required to produce an angular lateral displacement, distal to the applied force, of 30 degrees when applied at a distance of 10 mm from the distal end of the respective length of guidewire with the proximal end of the guidewire being laterally constrained."

Claim 1 now more clearly defines where and how the guidewire is secured prior to the application of the force, where the force is applied relative to where the guidewire is secured, and how the angular displacement is measured.

Specifically, when determining the stiffness of the guide wire, the proximal end of the guidewire is securely constrained. A force is then applied at a distance of 10 mm in a proximal direction from the distal end of that portion of the guidewire whose stiffness is to be determined. The magnitude of this force is increased until that portion of the guidewire distal to the point of application of force makes an angle of 30° with the original axis of the guidewire. The stiffness is thus defined as the magnitude of the applied force required to produce this 30° movement.

Regarding claim 18, the Examiner objects that it is unclear what the limitations in the claim add to the limitations of claims 1, 6 and 7. Claim 18 has been amended in accordance with the Examiners suggestion to correctly depend from claim 8. Support for this amendment may be found in the originally filed application in the passage of text extending from page 7, line 28 to page 8, line 2.

Regarding claim 20, the Examiner states that it is unclear whether the diameter in claim 20 is an inner or an outer diameter. Claim 20 has been amended to state that it is the external diameter of the catheter sheath which is guided into the bladder. Support for this amendment may be found in the application as originally filed, for example in the text extending from page 9, line 16 to page 10, line 5.

Regarding claim 21, the Examiner states that it is unclear what structure is described by “to penetrate the supra-pubic region of the human body...” Claim 21 has been amended to clarify that it is the catheter sheath which is adapted to penetrate the supra-pubic region of the human body. Support for this amendment may be found in the application as originally filed, in the paragraph of text bridging pages 9 and 10.

In view of the foregoing, it is respectfully submitted that claims 1-10, 18, 20, and 21 are not indefinite. Accordingly, withdrawal of this rejection is requested.

### ***Claim Rejections - 35 USC § 103***

Claims 1-10, 18 and 20 were rejected as being unpatentable over Cornish (U.S. Patent Publication 2002/0156397). Withdrawal of the rejection is respectfully requested for at least the following reasons.

The guidewire of the present application as now claimed in claim 1 is intended to be introduced into the supra-pubic region of the human body, and particularly into the bladder of a patient. Due to the nature of the supra-pubic tissues in the human body, the guidewire of the present application must have a specific stiffness characteristic. Further, the guidewire must have a different specific stiffness characteristic in different regions of the guidewire. This is because, in order to position the guidewire in the patient's bladder, it is necessary to initially insert a needle into the bladder by pushing the needle through the supra-pubic tissues so that it may enter the bladder. The guidewire may then be introduced into the bladder via the needle. This portion of the guidewire (the distal end) is relatively soft and floppy in order not to damage the patient's bladder. On the other hand, the proximal end of the guidewire has sufficient strength to support the sheath which is introduced into the bladder through the skin and tissue using the guidewire as a guide after the needle is withdrawn. For example, the guidewire of the present application exhibits an approximate stiffness of around 52 g/mm at the distal end and around 173.3 g/mm at the proximal end (see page 6, line 21 to page 8, line 2).

Cornish discloses a guidewire for use in coronary or vascular procedures and having a stiffness profile which changes or varies along its longitudinal length. The guidewire is configured to have a linear change in stiffness between its distal and proximal ends so as to improve the handling characteristics of the guidewire during insertion (see paragraphs 17, 24 and 50). In order to be able to insert the guidewire of Cornish into a patient's artery, the guidewire must necessarily be extremely flexible. Indeed, Figure 15 of Cornish indicates that a typical guidewire has a stiffness at its distal end of approximately 1 to 2 g/mm and at its intermediate portion of approximately 55 to 57 g/mm.

It is clear therefore that the guidewire of Cornish and the guidewire of the present application have very different stiffness characteristics which are dictated by their intended application. Consequently, it would not be possible to use the guidewire of Cornish in a supra-pubic application because the guidewire would not be sufficiently stiff to support the sheath that is used with the guidewire. There is no teaching or suggestion anywhere in Cornish of a guidewire which has sufficient stiffness support achieved in this manner.

Furthermore, the Examiner appears to have misunderstood the use of the definition of the stiffness with respect to the present application. It is necessary to include a means of defining the stiffness characteristic of the guidewire in order to be able to differentiate the guidewire of the present application from, for example,

guidewires intended for coronary or vascular procedures, such as the guidewire of Cornish. The definition of the stiffness does not merely quantify this parameter but defines specific ranges for the stiffness of the various portions of the guidewire of the present application, which enables it to perform its function.

It is respectfully submitted, therefore, that the Examiner is incorrect in stating that it would have been *prima facie* obvious to modify the guidewire of Cornish to obtain the claimed subject matter simply on the basis that such a modification would be considered to be a mere design consideration. Thus, even if the disclosure of Cornish were to be modified to include this definition of stiffness, it would still not be possible to arrive at the claimed subject matter, because the stiffness values of the guidewire of Cornish render it unsuitable for insertion into the supra-pubic region of the human body, and particularly into the bladder of a patient.

For at least the reasons set out above, the claimed subject matter is both novel and nonobvious over Cornish. Accordingly, withdrawal of this rejection is requested.

The absence in this reply of any comments on any other contentions set forth in the Office Action should not be construed to be an acquiescence therein. Rather, no comment is needed since the rejections should be withdrawn for at least the foregoing reasons.

### ***Conclusion***

In view of the foregoing, request is made for timely issuance of a notice of allowance.

Respectfully submitted,

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